UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,125	01/09/2001	Tadamitsu Kishimoto	053466/0296	6506

7590 12/13/2002

Harold C. Wegner
FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, DC 20007-5109

EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/13/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/756,125	Applicant(s) Kishimoto et al.
	Examiner G.R. Ewoldt	Art Unit 1644

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *5/06/02, 6/03/02, and 10/03/02*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *9-17* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *9-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The amendment, filed 5/06/02 has been entered.

2. Claims 9-17 are being acted upon.

3. In view of Applicant's amendment and response, filed 5/06/02, the previous rejections under 35 U.S.C. § 112, first paragraph, for lack of adequate written description (new matter) and regarding the deposit of the FERM BP-2998 hybridoma, have been withdrawn. Note that the declarations of Inventor Mihara regarding the deposit of the hybridoma FERM BP-2998 have been found acceptable.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9-17 stand rejected under 35 U.S.C.§ 112, first paragraph, because the specification, while being enabling for:

a method of inhibiting synovial cell growth comprising administering an antibody produced by FERM BP-2998,

does not reasonably provide enablement for:

a method of inhibiting synovial cell growth, or a method of treating chronic rheumatoid arthritis, comprising administering an antibody including a set of complementarity determining regions of the antibody produced by FERM BP-2998, for the reasons of record as set forth in Paper No. 11, mailed 12/04/01.

Applicant's arguments, filed 5/06/02, have been fully considered but they are not persuasive. First note that Applicant asserts, "As is well known in the art, the term "a set of complementarity determining regions" refers to a set of three complementary determinants contained in one chain of an antibody molecule." Absent any evidence of record, the aforementioned assertion is not considered to be well-known to the Examiner.

Regarding Applicant's arguments that "the Examiner jumps to a conclusion not supported by Bending," i.e., that the preparation of CDR-grafted antibodies is unpredictable, it remains the Examiner's position that the reference serves to demonstrate that it requires more than routine experimentation to create a CDR-grafted humanized antibody. It is noted that the specification discloses in detail the preparation of monoclonal antibodies, which might be considered by many to be routine, possibly because the Inventors realized the necessity of disclosing how to make the invention of the claims as originally filed. The method of the instant claims now requires the use of a humanized, CDR-grafted antibody, the preparation of which is not disclosed in the specification. Indeed, the CDR-grafted antibodies required by the method of the invention as now claimed, which must be considered much more complex and unpredictable to make than are routine monoclonal antibodies, are only vaguely disclosed in two brief paragraphs spanning pages 10 and 11 of the specification. Accordingly, it remains the Examiner's position that the specification fails to adequately disclose how to make the invention of the instant claims.

Regarding Applicant's argument that "In addition, the Examiner adopts a presumption inconsistent with the patent law. The Examiner wrongly assumes that the claimed subject matter must achieve "good" performance." It is the Examiner's position that, absent "good" performance, the method of the instant claims would be highly unpredictable for the treatment of chronic rheumatoid arthritis. Accordingly, the method of the instant claims would not be enabled for its intended use.

6. The following are new grounds for rejection.

7. Claims 9-17 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically: "an antibody including a set of complementarity determining regions of an antibody produced by FERM BP-2998."

Applicant's amendment, filed 5/06/02, asserts that support for the amendment can be found at page 11, lines 3-15, of the specification. However, the citation discloses only a vague and somewhat undecipherable teaching that framework regions of a human antibody might be substituted so that the "complementary determinant region" of a reshaped human antibody might form a suitable antibody binding site. Said disclosure does not provide support for the newly claimed sub-genus of a variety of antibodies derived from the antibody produced by the FERM BP-2998 hybridoma.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 8:00 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
December 13, 2002